

### **REMARKS**

Claims 1-4 and 7-22 were pending prior to this Response, with claims 18-22 having been withdrawn from further consideration. By the present communication, no claims have been added, claims 12-17 have been canceled without prejudice or disclaimer, and claims 1 and 9 have been amended to define Applicant's invention with greater particularity. Support for the amended claims may be found in the specification and claims as originally filed. Accordingly, claims 1-4 and 7-11 are currently under consideration.

### **Objections to the Specification**

Applicant respectfully traverses the objection to the specification for allegedly failing to capitalize trademarks used therein. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicant has amended the specification to capitalize all tradenames found therein. Withdrawal of the objection is respectfully requested.

### **Objections to the Claims**

Applicant respectfully traverses the objection to claim 9 as allegedly containing informalities. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicant has amended claim 9 to replace the alleged trademark with generic terminology and to insert appropriate punctuation. Withdrawal of the objection is respectfully requested.

### **Rejections under 35 U.S.C. §101**

Applicant respectfully traverses the rejection of claims 12-17 under 35 U.S.C. §101, as allegedly being directed to non-statutory subject matter. Specifically, the Office Action alleges that claims 12-17 provide for the use of a formulation, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to

encompass. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicant has canceled claims 12-17, rendering the rejection moot. Withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. §112, Second Paragraph**

Applicant respectfully traverses the rejection of claims 9 and 12-17 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have canceled claims 12-17, rendering the rejection moot as to these claims.

The Office Action alleges that claim 9 does not state that triclosan and alexidine are included as the active ingredients, while these compounds are required ingredients in the parent claim. Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicant has amended claim 9 to limit the active ingredient to triclosan. Withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. §103**

Applicant respectfully traverses the rejection of claims 1-4, 7-8, and 10-17 under 35 U.S.C. §103(a) as allegedly being unpatentable over Gaffar, *et al.* (U.S. Pat. No. 5,368,844; hereinafter "Gaffar"). Applicants have canceled claims 12-17, rendering the rejection moot as to these claims. The recent U.S. Supreme Court decision in the *KSR International v. Teleflex Inc.* (82 USPQ2d 1385), modified the standard for establishing a prima facie case of obviousness. Under the KSR rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

The Office Action alleges that Gaffar teaches oral compositions on dental surfaces with triclosan, comprising a liquid vehicle suitable for topically contacting dental surfaces and gums. However, Gaffar does not teach the viscosity and claimed concentrations. (Office Action, page 5). The Office Action further alleges that the amount of a specific ingredient is a result effective parameter that a person of ordinary skill in the art would readily optimize and that in the absence of some demonstration of unexpected results from the claimed parameters the optimization of ingredients would be obvious. (Office Action, page 5). Attached as Exhibit A is a submission based on data from a study which evaluated the use of the barrier formulation claimed in the present invention, as compared to a vehicle formulation, to demonstrate the effectiveness of the barrier formulation.

The second point in the discussion section of Exhibit A explains that the unique mechanism by which the test cream (*i.e.*, the barrier formulation of the present invention) works is by use of an active therapeutic moisturizing vehicle that retains triclosan at its intended site of action for a prolonged period. Therefore, the anti-microbial and anti-inflammatory effects of triclosan are given time to have significant clinical impact. Due to the nature of both the inflammation and infection, this phenomenon along with prolonged moisturizing has a synergistic effect, and thereby provides a highly effective treatment. The final point in the discussion section of Exhibit A also refers to the fact that the anti-microbial activity of the test cream is attributable to the presence of an effective amount of triclosan. Therefore, the effectiveness of the claimed barrier formulation is due to the specific amount of triclosan at the intended site of action, and the synergistic effect of the components is an unexpected result.

Applicant further submits that Gaffar does not specifically refer to the viscosity of the claimed oral composition. Therefore, Gaffar fails to identify viscosity as an important factor in the disclosed compositions. As such, Applicant submits that the viscosities of Gaffar's oral compositions can vary widely, depending on whether the composition is a gel, a cream or a liquid. Accordingly, it is highly likely that the viscosity of the oral compositions of Gaffar are more than 20 Pascal second, as evidenced by the Office Action's referral only to the liquid compositions in column 12, lines 28 -30 of Gaffar as having a viscosity less than 20 Pascal

second. By comparison, a viscosity of less than 20 pascal second is essential to the barrier formulation of the present application. As such, Applicants respectfully submit that Gaffar does not contain any suggestion or teaching of the claimed barrier formulation with the specified viscosity and the specific amount of active ingredient.

Even if one of skill in the art were motivated to adjust the concentrations of the ingredients of Gaffar, Applicant submits that one would have been faced with undue experimentation to arrive at the claimed invention since Gaffar fails to disclose any viscosity information as being relevant to the disclosed compositions, and a viscosity of less than 20 pascal-second is essential to the barrier formulation of the present invention. Accordingly, since the cited reference does not teach each and every limitation of the amended claims, Applicant respectfully submits that *prima facie* obviousness of the invention over Gaffar has not been shown by the Examiner, and requests withdrawal of the rejection.

Applicant respectfully traverses the rejection of claims 1-4, 7-8, and 10-17 under 35 U.S.C. §103(a) as allegedly being unpatentable over Littlewood, *et al.* (U.S. Pub. No. 2002/0034478 A1; hereinafter "Littlewood"). Applicants have canceled claims 12-17, rendering the rejection moot as to these claims. The Office Action alleges that Littlewood teaches an oral non-food composition with triclosan. However, Littlewood does not teach the concentrations of the present invention. (Office Action, page 6).

The arguments presented above with regard to Gaffar apply equally and are incorporated here. Specifically, Applicant submits that Littlewood does not specifically refer to the viscosity of the claimed oral composition. Therefore, Littlewood fails to identify viscosity as an important factor in the disclosed compositions. As such, Applicant submits that the viscosities of Littlewood's oral compositions can vary widely, depending on whether the composition is a gel, a cream or a liquid. Accordingly, it is highly likely that the viscosity of the oral compositions of Littlewood are more than 20 Pascal second, as evidenced by the Office Action's referral only to the viscosities of the individual components of the Littlewood compositions. By comparison, a viscosity of less than 20 pascal second is essential to the barrier formulation of the present application. As such, Applicants respectfully submit that Littlewood does not contain any

suggestion or teaching of the claimed barrier formulation with the specified viscosity and specific amount of active ingredient.

Even if one of skill in the art were motivated to adjust the concentrations of the ingredients of Littlewood, Applicant submits that one would have been faced with undue experimentation to arrive at the claimed invention since Littlewood fails to disclose any viscosity information as being relevant to the disclosed compositions, and a viscosity of less than 20 pascal-second is essential to the barrier formulation of the present invention. Accordingly, since the cited reference does not teach each and every limitation of the amended claims, Applicant respectfully submits that *prima facie* obviousness of the invention over Littlewood has not been shown by the Examiner, and requests withdrawal of the rejection.

Applicant respectfully traverses the rejection of claims 1-4, 7-17 under 35 U.S.C. §103(a) as allegedly being unpatentable over Littlewood, in view of Schulze zur Wiesche, *et al.* (WO 01/085,106 with U.S. Pub. No. 2003/0206933 A1 as translation; hereinafter “Schulze”) and Hansen, *et al.*, (U.S. Pat. No. 5,955,502; hereinafter, “Hansen”). The arguments presented above with regard to Littlewood apply equally and are incorporated here.

The Office Action relies upon Schulze for allegedly teaching agents for skin, in liquid form in aqueous dispersion, jojoba oil, liquid paraffin oils, stearic acid, aloe vera, silicones, Carbomer, and NIPA. The Action further relies upon Hansen for allegedly teaching agents for skin or mucosa with 1,2-triethanolamine, castor oil, and cetyl palmitate. Applicant respectfully submits that Schulze, concerning cosmetic agents with 2-furanone as the active ingredient, and Hansen, concerning use of fatty acid substances as bio adhesives, do not suggest inclusion of triclosan in the specific amount claimed in this application, and further do not identify viscosity as an important factor in formulating the respective compositions. Accordingly, one of the skill in the art would not have been motivated to combine Littlewood, Schulze, and Hansen to arrive at the claimed invention since it was not known that incorporation of triclosan in the range of 0.5-10% in a silicone based barrier formulation having the specified viscosity results in effective anti-microbial properties and benefits against conditions such as contact dermatitis, as shown by the description and data in respect of this application.

Even if one of skill in the art were motivated to combine Littlewood, Schulze, and Hansen, Applicant submits that doing so would not yield the claimed invention because none of the cited references disclose any viscosity information as being relevant to the disclosed compositions, and a viscosity of less than 20 pascal-second is essential to the barrier formulation of the present invention. Accordingly, since the combined references do not teach each and every limitation of the amended claims, Applicant respectfully submits that *prima facie* obviousness of the invention over Littlewood, Schulze, and Hansen, either alone or in combination, has not been shown by the Examiner, and requests withdrawal of the rejection.

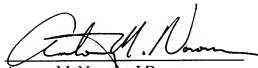
### CONCLUSION

In summary, for the reasons set forth herein, Applicants submit that the currently pending claims clearly and patentably define the invention and respectfully request that the Examiner withdraw all rejections and pass the application to allowance. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

The Commissioner is hereby authorized to charge \$230.00 as payment for the Petition for Two-Month Extension of Time fee to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-referenced Attorney docket number.

Respectfully submitted,

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Antony M. Novom, J.D.  
Registration No.: 45,517  
Telephone: (858) 638-6641  
Facsimile: (858) 677-1465

DLA PIPER US LLP  
4365 Executive Drive, Suite 1100  
San Diego, CA 92121-2133  
USPTO CUSTOMER NO. 28213